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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,807	01/22/2004	Stuart D. Shanler	132957.00101	4999
21269	7590	10/12/2007		
PEPPER HAMILTON LLP ONE MELLON CENTER, 50TH FLOOR 500 GRANT STREET PITTSBURGH, PA 15219			EXAMINER CARTER, KENDRA D	
			ART UNIT	PAPER NUMBER
			1617	
			NOTIFICATION DATE	DELIVERY MODE
			10/12/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketingpgh@pepperlaw.com

Office Action Summary	Application No. 10/763,807	Applicant(s) SHANLER ET AL.	
	Examiner Kendra D. Carter	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 4-6, 8-12 and 17-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7 and 13-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/20/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-11 and 13-16, oxymetazoline, and rosacea in the reply filed on June 20, 2007 is acknowledged. No reasons were given for traversal.

Claims 4-6, 8-12 and 17-24 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group and species, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made FINAL.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Particularly; the information disclosure statement contains hyperlinks in entries C23 and C25-C31.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 7, 13, 14 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Dejovin et al. (US 2004/0242588 A1).

Dejovin et al. teach a method of treating rosacea and the symptoms associated therewith, comprising topically administering to the skin of a patient in need of such treatment a composition comprising a therapeutically effective amount of at least one of an alpha-adrenergic receptor agonist (see claim 1; addresses claims 1, 2 and 7), specifically oxymetazoline (see claim 3; addresses claim 3). The composition is in the form of sprays, solutions, lotions, gels, creams, ointments, pastes, emulsions, and suspensions (see claim 6, addresses claim 14). The composition can include pharmaceuticals such as anti-inflammatory agents, anesthetics, analgesics, antibiotics and anti-infectives (see page 7, paragraph 73; addresses claim 13). A pharmaceutically acceptable topical formulation is any formulation which is pharmaceutically acceptable

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for topical delivery of the compounds of the invention. The choice of topical formulation will depend on several factors, including the nature of the symptoms to be treated, physiochemical characteristics of the particular compound of the invention and of other excipients present, their stability in the formulation, available manufacturing equipment and cost constraints (see page 11, paragraph 119). The formulations are topically applied directly to the affected area in any conventional manner will known in the art (see page 7, paragraph 77, lines 1-4). In regards to claim 16, the limitations are inherently taught because rosacea is treated by Dejovin et al. Additionally Dejovin et al. teach that triggers of rosacea are sun exposure, wind exposure, alcohol consumption, spicy foods, irritating facial cleansers, lotions and cosmetics (see page 1, paragraph 7, lines 5-8).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dejovin et al. (US 2004/0242588 A1) as applied to claims 1-3, 7, 13, 14 and 16 above in view of Yu et al. (US 2003/0108496 A1).

The teachings of Dejovin et al. are as applied to claims 1-3, 7, 13, 14 and 16 above.

Dejovin et al. does not specifically teach administering the composition in the form of a soap or cleansing bar.

Yu et al. teach compositions useful for treating a variety of cosmetic conditions and dermatological disorders, wherein the composition comprises a phenyl glycine derivative and a pharmaceutical topical agent such as oxymetazoline (see claims 1 and 42, line 53). Compositions comprising the phenyl-glycine compounds are beneficial for cosmetic conditions and dermatological indications associated with damages caused by extrinsic factors as sunlight, radiation, air pollution, wind, cold, dampness, heat, chemicals, smoke and cigarette smoking (see page 2, paragraph 15, column 1, lines 1-3, 11-14 and column 2, lines 1-2). Phenyl-glycine and its derivatives also are useful for

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cleansing the skin and soap preparations to improve skin redness (see page 3, paragraph 19, lines 1, 3, 9 and 10).

To one of ordinary skill in the art at the time of the invention would have found it obvious to and motivated to combine the method of Dejovin et al. and administering the composition in the form of a soap or cleansing bar because of the following teachings: 1) Dejovin et al. teach that the formulations are topically applied directly to the affected area in any conventional manner will known in the art (see page 7, paragraph 77, lines 1-4); 2) Dejovin et al. also teach that the choice of topical formulation will depend on several factors, including the nature of the symptoms to be treated, physiochemical characteristics of the particular compound of the invention and of other excipients present, their stability in the formulation, available manufacturing equipment and cost constraints (see page 11, paragraph 119); 3) Yu et al. teach phenyl-glycine compositions comprising a pharmaceutical agent such as oxymetazoline (see claims 1 and 42, line 53), which can be used for cleansing the skin and soap preparations to improve skin redness (see page 3, paragraph 19, lines 1, 3, 9 and 10). Thus, as Dejovin et al. teaches that the formulations can be any conventional manner, Yu et al. teach that oxymetazoline can be formulated with other agents useful for cleansing the skin and soap preparations. Therefore rendering claim 15 obvious.

Conclusion

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No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kendra D. Carter whose telephone number is (571) 272-9034. The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KDC



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

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